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SURVEY OF NAVY DENTAL CLINICS: MATERIEL COMPLAINTS REGARDING CARBIDE BURS AND LOCAL ANESTHETICS

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A survey of dental materiel complaints was conducted in response to SF-380 submissions from the field. Premature breakage of carbide-tipped dental burs represented up to 4% of bur usage Navy-wide. For specific clinics reporting a bur breakage problem, premature failure may account for 2.5 to 8% of total bur Significant Navy-wide problems with ineffective infiltration anesthesia were not uncovered. Excessive plunger friction and cartridge breakage was a problem for 8-9% of

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responding dental officers.

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SURVEY OF NAVY DENTAL CLINICS: MATERIEL COMPLAINTS REGARDING CARBIDE BURS AND LOCAL ANESTHETICS

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Research Progress Report NDRI-PR-86-04
Work Unit 63706N M0095.003-3028
Naval Medical Research and Development Command
Naval Medical Command, National Capital Region
Bethesda, Maryland 20814-5044

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Background

Recent review of current Reporting and Processing Medical Materiel Complaints/Quality Improvement Reports (SF-380), Figure 1, by the Naval Medical Command, revealed two recurring topics of concern and complaint. The first of these was the premature breakage of carbide-tipped dental burs. The second topic was the ineffective anesthesia reported for one particular brand of injectable lidocaine hydrochloride with epinephrine.

Descriptive comments from the SF-380 Reports provide insight into the clinician's view of these problems. Such comments on dental burs included the following, "Several doctors are experiencing frequent incidents of bur head separation. This usually occurs upon the initial contact of the bur with the tooth surface and neither appears to be a result of excessive pressure nor from incomplete bur seating in the handpiece. In approximately 50% of the incidents, the bur leaves the mouth as a projectile ...The repair department has checked the handpieces and there seems to be no problem with them." Comments regarding the local anesthetic included, "This inability to produce the desired effect cannot be ascribed to operator error. Repeated injections fail to anesthetize areas of infiltration with several operators attempting anesthesia."

Phone conversations between Naval Dental Research Institute (NDRI) staff and the complainants revealed that both the bur and anesthetic problems were perceived to be manufacturer-batch related. In most cases the complainants had experienced multiple episodes of the problem over the course of 8-12 months, prior to their filing SF-380 Reports. Thus the problems did appear to be episodic, reinforcing the complainants' belief that defects may have been manufacturer-batch related. The SF-380 Reports received by the Naval Medical Command do not appear to provide truly representative information about the frequency or nature of the problems, since these reports were generally not initiated until a problem had recurred.

A survey of Naval Dental Clinics was undertaken by NDRI. The purpose of the survey was to document the current frequency of dental bur and local anesthetic problems Navy-wide and to gain insight into the nature of any significant problems.

Protocol and Procedures

A two-page questionnaire was developed at NDRI with the cooperation of the Naval Hospital and Naval Dental Clinic, Great Lakes, Illinois. This form is reproduced as Figure 2. Copies of the questionnaire were provided to the Assistant Chief of Staff/Dentistry (ACOS/Dentistry) for each of the eight Geographic Commands of the Naval Medical Command for forwarding to representative dental clinics. A total of 137 forms was made available, with instructions that reproduction of the forms was acceptable as dictated by local distribution needs. The survey was initiated on 8 January 1985. It was requested, via the

ACOS/Dentistry, that completed forms be returned to NDRI by 1 March 1985.

Specific information regarding per capita bur usage by dental officers was obtained from detailed purchasing records maintained by the consultant for Operative Dentistry at Naval Dental Clinic, Great Lakes. Information as to the brands of carbide burs available through the Federal Stock System and the number of burs (specifically types #330 and #557) utilized by Navy dental activities during a specific period were obtained from transaction history files via the Defense Personnel Support Center, Philadelphia, Pennsylvania. Scanning electron (SEM) and light microscopic photographs were taken of a bur broken in clinical service, submitted by a clinician at Naval Dental Clinic, San Diego. Scanning electron microscopy facilities and technical consultation were provided by the Head of Dental Materials at a local dental school. Microscopic examination was also made of burs artificially broken at NDRI.

Discussions were held with staff of the American Dental Association (ADA) Councils on Dental Therapeutics and Dental Materials, Instruments and Equipment. These contacts were made to determine whether civilian dentists were voicing complaints similar to those expressed by Navy dentists as well as to discuss the general nature of the complaints in relationship to the ADA Specifications Program.

Results

NDRI received 143 completed forms during February and March 1985, many of which were photostatic copies of the originals. This rate of return (>100%) surpassed expectations.

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Responses to the specific survey questions appear in Table 1, both as raw data and as a percentage of responses per question. Since every respondent did not answer all questions the total responses do not always equal 143. Specific results (below) are grouped separately for burs and local anesthetics.

1. Dental Burs

Forty-eight percent of the respondents have experienced what they described to be premature breakage of carbide burs. Of this group, 63% complained of breakage at initial tooth contact and 25% within use on 1-3 patients. The number of incidents of premature bur breakage, recalle' as occurring over the last twelve months, is presented graphically in Figure 3. One hundred thirty-four usable questionnaire responses are presented. Non-numerical and inconsistent outlying numbers were not considered. All breakage occurred with carbide-tipped burs in high speed handpieces. Most respondents (93%) reported their last problem to have been within 1-3 months of the survey date.

Bur purchasing information obtained from NDC/GL can be used to estimate the number of carbide burs a dental officer uses per

year. With this number, the relation of premature bur failure incidents to the total bur usage can be calculated. The Operative Dentistry Consultant reports the purchase of 700 carbide burs by the Operative Department over a five month period. At an average of 40 dental officer-weeks per month the usage rate (both breakage and normal wear) averaged 3.5 burs/week/dentist. Extrapolated for 52 weeks (dental officer-weeks per month factors in leave and nonproductive time), average dental officer usage is calculated to be 182 burs/year. Figure 3 presents the premature breakage data normalized by the above calculations. According to these calculations, while premature breakage is not considered a problem for 52% of the clinics Navy-wide, it accounts for 2.5-8% of estimated total bur usage in 50% (interquartile range Q3-Q1) of the clinics reporting a problem. Navy-wide, premature bur breakage accounts for 0-4% of estimated bur usage in 50% (interquartile range Q3-Q1) of the respondent clinics.

Transaction document histories for carbide dental burs provided by Defense Personnel Support Center showed that 51,220 #330 burs (FSN 6520-01-2429) and 33,270 #557 burs (FSN 6520-01-003-7702) were issued to Navy dental activities during a recent 13-month period (15 March 1984 through 17 April 1985). These figures suggest that, Navy-wide, premature breakage affects up to 3120 burs (#330 plus #557) annually [(84,490 burs total) (4% breakage rate at the third quartile) (12/13 annually)]. At an average cost of \$.60 per carbide bur, premature breakage of #330 and #557 burs alone may cost the Dental Corps up to approximately \$1872 annually.

The burs most frequently complained of are #330 (44%) and #557 (26%). The remaining 30% of complaints were made against 10 other bur types as seen in Table 1. This bur distribution data is heavily weighted by relative usage rates and may not be indicative of design or material problems inherent to one bur type. Likewise, the breakdown by bur manufacturer, in Table 1, most likely reflects the ratio of burs available through the Federal Stock System. Defense Personnel Support Center reports that the brands of three manufacturers of dental burs are currently provided through the Federal Stock System.

Figure 4 is a scanning electron photomicrograph of a #245 carbide-tipped bur broken in clinical service. The fracture appears to have occurred through the carbide material quite close to the weld, possibly in a heat-affected zone of carbide (1). Brittle failure of the carbide was observed in all cases of burs artificially broken at NDRI.

Representatives of the American Dental Association Council on Dental Materials, Instruments and Equipment stated that complaints about premature bur breakage, involving a particular manufacturer, were received in 1982. The burs under question were found to have lower than allowed neck strengths under the American Dental Association Specifications Program. The Council was unaware of any recent problems involving premature breakage of burs.

2. Dental Anesthetics

Data from the anesthetic portion of the survey is found in Table 1. Problems in obtaining adequate infiltration anesthesia were reported by 22% of the respondents. Of those experiencing problems, 55% reported that they experienced 1-4 incidents over the last year. The anesthetic cited as a problem by most respondents was brand X 84%, followed by brand A 6.5%, and brand R 6.5%. It is likely that this distribution is also heavily weighted by usage rate, which is likewise dependent upon brand availability through the Federal Stock System. Fifty-eight percent of the dentists reporting ineffective anesthesia episodes were able to achieve adequate anesthesia by switching to other containers of the same anesthetic. Seventy-seven percent were able to achieve adequate anesthesia by switching to a different This information supports the assumption that some ineffective anesthesia problems may be manufacturer-batch related in nature.

The staff of the American Dental Association Council on Dental Therapeutics was not aware of any recent problems involving local anesthetics.

3. Anesthetic Cartridges

Specific problems with cartridges were reported by 25% of the respondents. The most common complaints were about excessive plunger friction (9%) and cartridge breakage during injection (8%). Plunger friction complaints were not anticipated during the design of the survey; therefore, this relatively large response is most interesting. Again, brand X was most frequently implicated, but the interpretation of this result is not straightforward. Other cartridge problems (broken cartridges in the sealed package, particulates in the solution, excessive oxidation of the cartridge cap) were infrequently mentioned.

Discussion

1. Dental Burs

Interpretation of the information obtained via the survey indicates that there may be a significant problem with premature breakage of carbide-tipped dental burs in Naval Dental Clinics. The situation encountered is separation of the carbide tip from the steel shank, with the tip possibly becoming a potentially hazardous projectile. The broken bur tip may potentially lodge in tissues of the mouth or eye, or be swallowed or aspirated by the patient. Separation occurs most often at high speed, upon initial contact of the bur with the tooth or restoration, indicating an inherent weakness in the bur rather than fatigue-failure or misuse being the cause.

SEM and light microscopy show that fracture seems to occur in the tungsten carbide tip, very near the weld to the steel shank. This failure location may be a zone in the tungsten carbide which is adversely affected by the welding process. The welding process is a proprietary technique involving heat, electrical induction and pressure to join the tungsten carbide "pill" to the steel shank. Further research may be warranted to identify any physical property changes which may occur in the hypothesized "heat affected zone" of failed versus non-failed burs.

The apparent predisposition of #330 and #557 burs to break prematurely may reflect the majority usage of these burs in conventional restorative technique. Additionally, these burs are often used to remove failed amalgam and composite restorations as well as to prepare enamel and dentin structure. Use of these carbide burs to remove amalgam can result in "snatching" even if only slight pressure is applied. On occasion "snatching" may lead to fracture of the bur when the cutting edges dig into the restoration and lock the movement of the bur, causing it to shear and break (2).

ADA specification #23³ only indirectly addresses bur breakage. The specification directs measurement of bur neck strength under a designated load as the bur is held stationary. No breakage or distortion less than a maximum permanent set is specified. It is recognized that this test probably does not predict clinical characteristics of bur neck strength or failure due to brittleness of the carbide tip during bur rotation (4). The nature of bur failure may be quite different under clinical loads at 300,000 to 400,000 revolutions per minute than under stationary loading conditions, due to added torsional force effects and phenomena due to possible impact loading (5).

NDRI is currently working in consultation with the ADA Council on Dental Materials Instruments and Equipment to develop a bur breakage test simulating clinical usage conditions. The bur designs and brands available to Naval Dental Clinics will be tested. Also, the effect that the material being cut has upon breakage of dental burs will be evaluated.

2. Dental Anesthetics

Ineffective local anesthetic episodes do not appear to be a significant Navy-wide problem. Some operators have experienced sporadic and infrequent episodes of ineffective infiltration anesthesia. Operator technique, pharmacological variables and patient variability, especially psychologic factors, make it difficult to assess cause-and-effect relationships (6). Kaufman and others (6) found that 90% of the dentists they surveyed, over a five-day period, reported some anesthetic failure during restorative visits. Anesthetic failure occurred in 13% of all patients seen in the five-day period, and about five anesthetic failures occurred each week in a general practice. In this regard, the results of the survey of Navy Dental Clinics (22% reporting problems of ineffective anesthesia during the last 12 months) compare quite favorably.

A particular lot or batch of anesthetic was not implicated. The association frequency of brand X with episodes of ineffective anesthesia is probably not meaningful considering its majority usage in Naval Dental Clinics. The premise originated by the SF-380 Reports that anesthetic failures were related to a particular brand or batch of local anesthetic was not clearly supported. It should be noted, however, that the survey results represent a snapshot of current conditions. Problems that existed when SF-380 Reports were generated may have been resolved and may recur.

3. Anesthetic Cartridges

Plunger friction and cartridge breakage may be related events. The plunger is designed with low tolerance to fit the glass sides of the carpule so that a hermetically sealed product is assured. Excessive plunger friction during injection may conceivably result in breakage of the glass cartridge due to the large force required to move the plunger along the glass wall. The United States Air Force Dental Investigative Services reports that a recent problem involving excessive plunger friction in Air Force dental clinics was tracked by the Federal Drug Administration to a malfunction in the manufacturing process, i.e., the misdirection of nozzles which spray a silicone lubricant onto the plunger (7).

Cartridge breakage can sometimes result due to the use of a badly worn syringe, a bent harpoon, a syringe not designed to take a 1.8 ml cartridge, or a needle which is bent at its proximal end (8). Cartridges with extruded plungers should not be used. An extruded plunger can lose its lubrication and can be forced back into the cartridge only with difficulty, possibly resulting in cracking of the glass cartridge (9). One manufacturer advises that dental cartridges should not be autoclaved because the closures employed cannot withstand autoclaving temperatures and pressures (9). Prudence dictates abandoning the injection procedure if excessive plunger friction is encountered. Cartridge manufacturers are now producing Mylar-wrapped cartridges to decrease the risk of cartridge breakage during injection.

Summary and Conclusions

A survey of dental materiel complaints was initiated by NDRI, in response to a NAVMEDCOM request concerning SF-380 submissions. Premature breakage of carbide-tipped burs may account for 0-4% of bur usage Navy-wide, amounting to a potential loss of up to 3120 burs annually. For specific clinics reporting a breakage problem, premature failure may account for between 2.5-8% of total bur usage. NDRI is in the process of developing a test to eval the bur breakage under clinically simulated conditions to provide data for more realistic acceptance standards. This survey did not uncover any significant Navy-wide problems with ineffective infiltration anesthesia. Reasons for the infrequent scattered episodes of ineffective anesthesia reported are not provided by the results of this survey.

Excessive plunger friction and cartridge breakage was a problem for 8-9% of dental officers responding.

Acknowledgement

The authors thank LCDR G. Jones of NDC Great Lakes for the bur purchasing data, CDR W. DiZinno of NDC San Diego for contributing the bur broken in clinical service, G. Probst of Defense Personnel Support Center for the transaction history files for the #330 and #557 burs, and W. Brantley of Marquette University Department of Dental Materials for his technical expertise and use of the scanning electron microscope. We also wish to thank the Assistant Chief of Staff/Dentistry officers of the eight Geographic Commands of the Naval Medical Command for their assistance in the distribution and follow-up of the forms which resulted in the timely and universal survey return.

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TABLE I

DATA FROM SURVEY OF DENTAL MATERIEL COMPLAINTS *

I. DENTAL BURS

1. Has your clinic experienced premature breakage of any dental burs?

	Yes	: 69	(48%)			No: 74 ((52%)	
2.	Α.	Federal	Stock	#:				
	652 652	0-01-003 0-01-003 0-01-003	3-7702 3-3915	23 18 4 3	(42%) (33%) (7%) (5%)	6520-01-00 6520-01-00 6520-01-00)3-2318)3-7701	2 (4%) 2 (4%) 2 (4%) 1 (2%)
	В.	Manufac	turer:					
		Company	, A	34	(55%)	Company B	2	8 (45%)
	С.	Type:						
		330 557 245 56 701 57	33 21 6 4 3	(44%) (26%) (7%) (5%) (3%) (3%)		558 169L 170 699 700 35	3 (3%) 2 (2%) 2 (2%) 2 (2%) 1 (1%) 1 (1%)	
	Car	bide:	59 (100%)	Steel:	(0%)	Diamond:	(0%)

D. Manufacturer's identifying numbers (lot, serial, control):

DLA-120-82-D-4320 DLA-120-83D-4134-001 DLA-120-81D-4396 6843-15001 6843-15052	8 7 3 3 2	Company (21%) (18%) (8%) (8%) (5%)	A DLA-120-84-4371-0001 0856-1282 6843-16887 79250 81096	1 1	(3%) (3%) (3%) (3%) (3%)
107-007-010 237-001-008 3967	5 3 1	Company (13%) (8%) (3%)	B 4187 3279	1	(3%) (3%)
E. Date of last proble	m:				
FY 84 2nd Quarter 3rd Quarter 4th Quarter	2 1 1	(3%) FY (2%)	85 1st Quarter 2nd Quarter	22 33	(37%) (56%)

F. Number of occurrences in the last 12 months: (# of occurrences : frequency)

0	:	74	(52%)	6:	5 (3%)	14	:	1	(1%)	45 :	3	(2%)
1	:	1	(1%)	7:	3 (2%)	15	:	5	(3%)	50 :	•	1 (1%)
2	:	4	(3%)	10:	2 (1%)	17	:	1	(1%)	104 :	•	(1%)
3	:	4	(3%)	11:	1 (1%)	20	:	4	(3%)	208 :	2	(1%)
4	:	6	(4%)	12:	10 (7%)	24	:	3	(2%)	360 :	•	(1%)
5	:	3	(2%)	13:	1 (1%)	30	:	1	(1%)			
Non	– r	วนพ	erical	respons	es, e.g.,	nume	r	us	, many,	frequent	:	6 (4%)

3. Conditions under which breakage occurred:

Α.	Handpiece:	High speed Low speed	60 1	(99%) (1%)
В.	Longevity:	Initial contact	52	(63%)
		1-3 patients	21	(25%)
		>3 patients	9	(11%)
		Refore contact	1	(14)

4. Location of breakage:

Α.	Head separation from shank	58	(85%)
В.	Neck of shank	7	(10%)
С.	In flutes	3	(5%)
D.	Other shank location	0	(0%)

II. DENTAL ANESTHETICS

1. Has your clinic experienced unusual problems with infiltration anesthesia related to any particular brand of local anesthetic?

	Yes	28	(22%)	No	100	(78%)
2.	Α.	Manufacturer:				

B. Brand Name:

Brand A	27	(85%)	Brand	С	2	(6%)
Brand B	2	(6%)	Brand	D	1	(3%)

Company Y 4 (12%)

C. Generic Description:

Company X 28 (87%)

Lidocaine 28 (90%) Prilocaine 1 (3%) Mepivacaine 2 (7%)

D. Lot #:

		Company X Lidocaine			
175 402035	3	(18%)	175 306027		1 (6%)
175 402006	2	(12%)	175 401048		1 (6%)
175 307007	2	(12%)	175 402002		1 (6%)
175 401045	2	(12%)	175 308037		1 (6%)
175 404004	1	(6%)	540 307698		1 (6%)
		Company Y Mepivacaine			
1143/2065	1	(6%)	4114	1	(6%)

E. Expiration Date:

10/86	1	(5%)	2/85	1	(5%)	7/84	1	(5%)
8/85	8	(40%)	1/85	2	(10%)	4/84	1	(5%)
7/85	4	(20%)	12/84	1	(5 %)	10/83	1	(5%)

3. How many times has your clinic experienced a problem in the last twelve months? (Occurrences in last twelve months / Respondents)

0 / 100	(78%)	7 / 1	(1%)	16	/ 2	(1%)
1 / 5	(3%)	9 / 1	(1%)	18	/ 1	(1%)
2 / 5	(3%)	10 / 1	(1%)	35	/ 1	(1%)
3 / 4	(3%)	11 / 1	(1%)	50	/ 2	(1%)
4 / 2	(1%)	12 / 1	(1%)	100	/ 1	(1%)
Non-nume	ric respon	ISPS. P.F.	frequent	. 1	(1)	%)

4. Were doctors able to achieve adequate anesthesia by switching to another container of the same anesthetic?

```
Yes 18 (58\%)
No 10 (32\%)
Did not attempt with same brand 3 (10\%)
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5. Were doctors able to achieve adequate anesthesia by switching to a different brand?

```
Yes 23 (77%)
No 2 (7%)
Did not attempt with different brand 5 (17%)
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III. DENTAL ANESTHETIC CARTRIDGES

1. Has your clinic observed any of the following conditions in the last twelve months?

No Problems noted	102	(75%)
Broken cartridges in freshly opened containers	3	(2%)
Cartridge breakage during injection	11	(8%)
Unusual oxidation of cartridge cap	4	(3%)
Discoloration of solution	1	(1%)
Particulates in solution	3	(2%)
Other (excessive plunger friction)	12	(9%)

2. A. Manufacturer:

Company X	17	(94%)	Company Y	<u>.</u>	1 (6%	;)
B. Brand Na	ame:					
Brand A	17	(94%)	Brand B		1 (6%	(;)
C. Generic	Descri	ption:				
Lidocaine	17	(94%)	Mepivacai	.ne	1 (6%	;)
D. Lot #:						
175402006 175402035 175401045 175403115	3 (23%) 23%) 15%)	402035 406046 4019	1 1 1	(8%) (8%) (8%)	
E. Expirati	on Dat	·e:				
	(18%) (64%)		2/86 1 6/86 1	(99 (99		

^{*} Percentage figures are rounded to the nearest whole number.

FIGURE 1.

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FIGURE 2. SURVEY OF DENTAL MATERIEL COMPLAINTS

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Note: If your clinic is experiencing problems with multiple products, please reproduce this form and submit additional copies as needed.

<u>I</u> .	DENTAL BURS
1.	Has your clinic experienced premature breakage of any dental burs? [] YES [] NO
(If	no, please continue with sections II. & III. DENTAL ANESTHETICS)
2.	Federal Stock #: Manufacturer: Type (i.e., 330 FG): [] carbide [] steel [] diamond Manufacturer's identifying numbers (i.e., lot, serial, control):
	Date last problem: Number of occurrences in last 12 months:
3.	Conditions under which breakage occurred:
	Handpiece [] High speed [] Low speed
	Longevity [] Initial contact [] 1-3 patients [] More than 3 patients
4.	Location of breakage: [] Head separation from shank [] Neck of shank [] Other shank location
	Comments:
Pho	tal Officer (please print): ne # (Auto/Com.): / nic Name and Location:

II. DENTAL ANESTHETICS

<pre>l. Has your clinic experienced unusual problems with infiltration anesthesia related to any particular brand of local anesthetic: [] YES [] NO</pre>
2. Manufacturer: Brand Name: Generic Description: Lot #: Expiration Date:
3. How many times has your clinic experienced a problem in the last twelve months?
4. Were doctors able to achieve adequate anesthesia by switching to another container of the same anesthetic? [] YES [] NO [] Did not attempt with same brand
5. Were doctors able to achieve adequate anesthesia by switching to a different brand? [] YES [] NO [] Did not attempt with different brand
Comments:
III. DENTAL ANESTHETIC CARTRIDGES
<pre>1. Has your clinic observed any of the following conditions in the last twelve months? (Please check all that apply per any one brand.)</pre>
Comments:
2. Manufacturer: Brand Name: Generic Description: Lot #: Expiration Date:
Dental Officer (please print): Phone # (Auto/Com.): Clinic Name and Location:
Date:

(PERCENTAGE OF ESTIMATED ANNUAL BUR USAGE) 100 20 30 50 80 70 80 90 10 40 0 ANNUAL FREQUENCY OF REPORTED PREMATURE BUR BREAKAGE 8 (5.5) (11.8) (18.5)(22.0) (27.5)(38.5) (44.8) (48.5) (54.9) (33.8) 134 USABLE QUESTIONNAIRE RESPONSES 67 ORDERED BY 134

FREQUENCY OF PREMATURE BUR BREAKAGE

FIGURE 3. 134 USABLE QUESTIONNAIRE RESPONSES ORDERED BY ANNUAL FREQUENCY OF REPORTED PREMATURE BUR BREAKAGE

CUMULATIVE PERCENTAGE OF RESPONSES

-100%

- 70x - 50x

-80%

--9**0**%



FIGURE 4. S.E.M. OF THE FRACTURED SURFACE OF A #245 CARBIDE BUR BROKEN IN CLINICAL USE.